

# IACP Board of Directors Meeting

22 October  
2003

## STATE UPDATE

IACP continues to monitor compounding-related developments at the state level. Since June 2003, IACP has reviewed and written comments on compounding regulations in Iowa and Arkansas. A brief summary of the comments follows below. The full-text comments are attached.

IACP is currently working to review and submit comments on draft sterile and non-sterile regulations for Texas pharmacists. In addition, the Texas Board of Pharmacy recently cited an IACP member pharmacy for compounding for animals from bulk drug substances. IACP strongly objects to the Texas Board of Pharmacy's interpretation of Federal Standard 530.13, the rule referenced in the citation. IACP, along with the Texas Pharmacy Association (TPA) and the National Community Pharmacists Association (NCPA), sent a letter to the Texas Board of Pharmacy objecting to this citation. A copy of this letter is attached.

Further, IACP recently updated our state board of pharmacy contacts roster. We will now send a letter to each Board of Pharmacy to ensure that we are on the Board's mailing list to receive updates relevant to compounding.

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### Iowa

The Iowa Board of Pharmacy recently developed new labeling requirements for compounded prescriptions. The labeling requirements were approved during the June 2003 meeting of the Iowa Board. IACP has submitted comments to the Board outlining two concerns with the labeling requirements.

Initially, the labeling rule requires the name of the patient to be listed on the label. IACP was concerned that this requirement could preclude office use compounding. However, the Iowa Board has assured us that the section applies only to products dispensed to an ultimate user and will not affect office use products.

Secondly, IACP encouraged the Iowa Board to replace its term "bulk drug substance" with "active pharmaceutical ingredient." The labeling rule requires Iowa pharmacists to list the name and quantity of each bulk drug substance contained in the product on the label. Although Iowa defines "bulk drug substance" to include only active ingredients, the term "bulk drug" is used in many other contexts in pharmacy regulations. Likewise, IACP has encouraged the Iowa Board to use the term active pharmaceutical ingredient in its regulations for sake of clarity and consistency.

IACP's comments will be considered by the Iowa Board during upcoming committee and Board meetings.

### Arkansas

During its June 2003 meeting, the Arkansas Board of Pharmacy adopted several emergency amendments to existing compounding regulations. These amendments require sterility, endotoxin, and potency testing for compounded sterile products meeting certain criteria and prohibit office use compounding for veterinarians. These amendments went into effect immediately. However, the Board will consider revisions to these amendments during its October 2003 Board meeting.

The Arkansas Board has also published several additional amendments that will be considered during the upcoming October 2003 Board meeting. These amendments primarily related to compounding of commercially available products.

IACP has submitted comments to the Arkansas Board of Pharmacy related to these amendments.



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PROTECTING PROMOTING AND ADVANCING PHARMACY COMPOUNDING  
*International Academy of Compounding Pharmacists*

## Iowa Comments

August 29, 2003

Iowa Board of Pharmacy Examiners  
c/o Terri Witkowski, Administrative Assistant  
400 S.W. Eighth Street, Suite E  
Des Moines, IA 50309-4688

**RE: IOWA PROPOSED AMENDMENTS TO SECTIONS 10(6), 10(7), AND 10(8) OF CHAPTER 20,  
"PHARMACY COMPOUNDING PRACTICES"**

Members of the Iowa Board of Pharmacy:

The International Academy of Compounding Pharmacists ("IACP") appreciates the opportunity to comment on proposed amendments to Chapter 20, "Pharmacy Compounding Practices." IACP's mission includes increasing awareness of the importance of compounding by providing accurate information on the benefits of compounding and providing assistance to pharmacists in improving their compounding activities. In this capacity, IACP wishes to address several concerns related to these regulations. IACP submits these comments on behalf of its Iowa members, who will be directly impacted by these regulations, and additionally their patients, who benefit from compounded medications.

IACP has two primary concerns with proposed Iowa regulations:

**657 – 20.10(6) (c) – "The name of the patient or, if such drug is prescribed and compounded or an animal, the species of the animal and the name of its owner"**

Requiring a patient name on all compounded drug products could potentially preclude the compounding of products for physician office use or office administration. The Iowa Board of Pharmacy provides for this important practice in existing pharmacy regulations (see 20.3(4)). Compounding for physician office use is an invaluable service provided by pharmacists to physicians and should be maintained. However, it is not always feasible to label a product with a specific patient's name when providing practitioners with products to administer in the course of their professional practices.

Initially, there are many cases where it would be impractical to compound an individual dose of a physician-administered compound for a specific patient. For example, Cantharidin is a product recognized by FDA on its proposed "List of Drug Substances That May Be Used in Pharmacy Compounding," with the restriction that cantharidin be administered "in the professional office setting only."<sup>1</sup> Cantharidin is administered topically in the treatment of warts. Treatment may require only one drop per patient. Likewise, it would be virtually impossible to accurately compound a patient-specific dose of cantharidin or any medication requiring a similar quantity administration. Instead, physicians order a vial of this medication from pharmacies and administer single doses to individual patients as needed. Such multiple dose vials could not be labeled with a specific patient's name.

In addition, office use compounds are often drug products that must be compounded in advance and must be available for immediate administration by the physician. In many cases, the physician cannot anticipate the need for emergency dosage forms, nor wait for the pharmacy to prepare and test a compound to meet an unanticipated need. The physician instead maintains a small supply of these

<sup>1</sup> 64 Fed. Reg.998, 1002 (Jan. 7, 1999)



compounds to address emergency situations. Again, it would be impossible for pharmacies to compound these dosage forms for a physician and label such products with a patient name.

It is our understanding that the Iowa Board presently allows pharmacists to provide office use compounds of this nature to physicians. However, the proposed labeling rule, as written, may require pharmacists to cease providing this valuable service or to disregard this labeling rule to provide such products.

Likewise, IACP requests that the Board provide an exemption from the patient name requirement for office use products. This exemption may be provided in the introduction to the labeling section, alongside the exemption for sterile compounded products, or it may be added as a provision in 20.10(6) (c).

**657 – 20.10(6) (g) – “The name and quantity or percentage of each bulk drug substance contained in the compounded drug product”**

As written, this requirement may be problematic. The term bulk drug substance can be interpreted as including active ingredients as well as inactive ingredients or excipients. Iowa has specifically defined bulk drug substance as “any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packing of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances” (See 657-20.2). However, this definition of bulk drug substance is not widely understood among pharmacy practitioners. IACP is concerned that use of this term in Section (g) may create confusion among pharmacists.

Many pharmacists may interpret Section (g) to require documentation of each active ingredients, as well as inactive ingredients or excipients that are included in a compounded product. Documenting the name and percentage of each active and inactive ingredient in a compounded product would not be feasible in many instances. Many compounded drug products contain numerous ingredients. Names of active and inactive ingredients are often lengthy and in many instances it would be impossible to fit the name of every ingredient in a compound in the limited space available on prescription labels. In addition, many compounded drug products are packaged in small container that could not accommodate more than one label to compensate for overflow on the original label.

The intent of this regulation is that the name and quantity of each active pharmaceutical ingredient contained in a drug product should be documented on the label. Likewise, Iowa’s labeling requirements would be much less ambiguous if the requirement was updated to use a term, such as active pharmaceutical ingredient, that is consistent with other pharmacy regulations.

IACP appreciates the opportunity to share our concerns with the Iowa Board of Pharmacy and we look forward to working with you on any future issues related to pharmacy compounding that we might encounter. If we can be of any assistance, or if you have any questions, please do not hesitate to contact me or Jennifer Goodrum, IACP’s Regulatory Affairs Coordinator, at (281) 782-9424.

Sincerely,

L.D. King  
Executive Director



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PROTECTING PROMOTING AND ADVANCING PHARMACY COMPOUNDING  
*International Academy of Compounding Pharmacists*

## Arkansas Comments

September 4, 2003

Arkansas Board of Pharmacy  
c/o Charlie Campbell, Executive Director  
101 East Capitol, Suite 218  
Little Rock, AR 72201

**RE: Emergency Changes to Regulation 7-02: "Compounding"**

Members of the Arkansas Board of Pharmacy:

The International Academy of Compounding Pharmacists ("IACP") appreciates the opportunity to comment on recent changes to regulation 7-02, "Compounding." IACP's mission includes increasing awareness of the importance of compounding by providing accurate information on the benefits of compounding and providing assistance to pharmacists in improving their compounding activities. In this capacity, IACP wishes to address a number of concerns related to these regulations. IACP submits these comments on behalf of its Arkansas members, who will be directly impacted by these regulations, and additionally their patients, who benefit from compounded medications.

IACP's concerns with the emergency changes to Regulation 7-02 will be addressed by section:

**07-02-0001 Purpose and 07-02-0002 (a): "Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug product that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (i.e. hypersensitivity to excipients or preservative in the FDA-approved product)."**

Initially, IACP is concerned with the provision in the introduction to Regulation 07-02-0001 and in Regulation 07-02-0002 (a) that addresses the compounding of commercially available products. While IACP generally supports the notion that a pharmacy should not compound exact copies of commercially available products, IACP is concerned that the Arkansas regulations may be overly restrictive.

To begin, IACP is concerned with lack of definition of the phrase "commercially available FDA-approved drug product." The Arkansas Board should clarify that a product is not commercially available if health care providers cannot obtain the product from an FDA-approved manufacturer. In many instances, pharmacies compound drugs that are in short supply, are temporarily unavailable, or, although they have not been withdrawn for safety reasons, are off the market. If a pharmacist receives prescriptions for copies of FDA-approved drugs, is told by the health care provider that the health care provider is unable to obtain the FDA-approved product through normal chains of commercial distribution, and the pharmacist verifies this status, the pharmacist should be permitted to compound the product. Otherwise, patients will be denied access to necessary medications. Unfortunately, many drug products that have been approved by FDA are in short supply or are temporarily not being produced; compounding by pharmacists can fill these gaps.

Arkansas has addressed such situations in a subsequent amendment (see 07-02-0002 (I) (8), "The unavailability of such drugs must be documented prior to compounding. The recommended methodology



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**PROTECTING PROMOTING AND ADVANCING PHARMACY COMPOUNDING**  
*International Academy of Compounding Pharmacists*

IACP002144

for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested on audit.”) However, for clarity, the Board should consider consolidating all definitions and exceptions related to the compounding of commercially available products into these introductory sections. Likewise, the exception for unavailability should be provided in the introductory sections.

Additionally, IACP is concerned with the ambiguity inherent to the term “slightly different” used in the regulation cited above. The Board’s definition of a product that is “slightly different” than a commercially available product is critical to the interpretation and enforcement of this statute. However, the Board has provided little to no guidance on what constitutes “slightly different.”

Further, the Board has definitively limited cases of patient need to “hypersensitivity to excipients or preservatives.” However, there are many additional patient needs that would justify the use of a compounded product. Patients may require a compounded product when a specific strength or route of administration is not commercially available, when the physician requests that an additional ingredient be added to a product that is commercially available, or when patient compliance is tied to a compounded formulation. A Board of Pharmacy cannot anticipate every situation that might require the use of a compounded drug product. Thus, the designation of patient need for a compounded medication should be left to the prescribing physician’s discretion.

To address these concerns, IACP recommends that the Arkansas Board of Pharmacy rewrite the second sentence of the regulation cited above. The Board should provide the following Congressional exceptions for the compounding of commercially available products: the term ‘essentially a copy of a commercially available drug product’ does not include a drug product in which there is a change which produces a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.”<sup>2</sup> This definition and strategy for addressing the compounding of commercial products has been endorsed by Congress, and the Arkansas Board should similarly adopt it.

A prescription from a licensed practitioner for a compounded drug should be sufficient documentation of need for a compounded product. It is inappropriate for the Arkansas Board to demand more documentation from a licensed practitioner of the medical need of a particular patient. Pharmacists have never been required to receive documentation of medical need beyond the prescription. IACP believes that requiring physicians to justify the decision to prescribe a particular drug for a patient is without any statutory basis. Physicians are free to prescribe off-label uses without documentation.<sup>3</sup> They are equally free to prescribe compounded medication without written explanations.<sup>4</sup>

IACP foremost recommends replacement of the second sentence of this section addressing commercially available products. However, if the Board maintains the parenthetical statement at the conclusion of this section in any form, the abbreviation “i.e.” should be changed to “e.g.” and the Board should list several additional examples of valid patient needs. The abbreviation “i.e.” is explanatory and limits interpretation

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<sup>2</sup> This is the definition for commercially available products chosen by Congress in FDAMA 503A. Congress’ definition did refer to an “identified individual patient.” This language could have been construed as precluding compounding for office use. Since, FDA has since omitted the phrase “individually identified” in similar language in its CPG. IACP strongly supports omission of this phrase.

<sup>3</sup> 21 C.F.R. § 312.2(d).

<sup>4</sup> This element also creates an extraordinary practical challenge: how to evaluate a physician’s rationale. It places the Arkansas Board of Pharmacy in the unprecedented position of second-guessing decisions by doctors, effectively leading the Board of Pharmacy to regulate the practice of medicine. Likewise, the prescription should suffice; nothing more is needed.



to the specific case cited. On the other hand, the abbreviation “e.g.” introduces examples of a concept and leaves room for additional cases.

#### 07-02-0001 (5)

IACP is strongly opposed to the Arkansas Board’s sole reliance on end-product testing, as the means for assuring sterile product quality. Regulation 07-02-0001, Section (5) sends a false message to Arkansas pharmacists that end-product testing alone provides sufficient quality assurance for compounded sterile products. However, placing emphasis or dependence on end-product testing is a fundamentally flawed approach to the regulation of sterile compounding practices, as end-product testing is only partially effective for assuring product quality.

Scientific literature and sterile product experts contend that end-product testing is a poor indicator of product quality. Statistics provided in Remington’s: Pharmaceutical Sciences<sup>5</sup> indicate that end-product testing fails to identify contamination in a batch up to 60% of the time when a pharmacy tests half of every batch compounded. Remington’s indicates that the only method of assuring product quality using end-product testing would be to test every product compounded. Pharmacists could not test every product compounded, as testing consumes the product needed to dispense to a patient. Thus, over-reliance on end-product testing is an extremely poor indicator of product quality. End-product testing is appropriately utilized as an indicator in a much broader quality assurance program endorsed by a pharmacy.

Likewise, IACP strongly endorses process, personnel, and equipment validation as excellent indicators of sterile product quality. Pharmaceutical experts contend that the integration of systematic process controls in a compounding pharmacy is the ideal means of verifying product quality. “‘Systematic process control’ is defined as validated policies, procedures, and processes that are used to consistently produce products of the highest quality.”<sup>6a</sup> Systematic process controls include:

- Compliance with operating policies, procedures and processes and the documentation generated from their execution;
- Initial and ongoing employee education using didactic, practicum and on-the-job training strategies;
- Personnel controls such as proper handwashing, gowning and gloving procedures and successful aseptic technique (i.e. media fill) validation; and
- Air surface sampling tests of critical work areas.<sup>5b</sup>

Monitoring and evaluation of data generated from these operations can provide a comprehensive picture of product quality and facility aptitude for sterile compounding operations.

Endorsement of systematic process controls would involve a greater emphasis on activities such as media fills, equipment validation, process validation, and environmental quality sampling. If processes, personnel, and environment have been validated, the Arkansas Board of Pharmacy, the pharmacy preparing sterile products, and the public should have a high degree of confidence in the final product

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<sup>5</sup> Osol A (ed). *Remington’s: Pharmaceutical Sciences*. Easton, PA: Mack Publishing Company. 1980; 16: 1400-1402.

<sup>6</sup> For a comprehensive discussion of the merits and implementation of systematic process controls for sterile pharmacy compounding operations, please reference the following articles:

<sup>a</sup> Kastango ES, Douglass K. Quality Assurance for Sterile Products. *International Journal of Pharmaceutical Compounding*. 2001; 5: 246-253.

<sup>b</sup> Kastango ES, Douglass K. Improving the Management, Operations, and Cost Effectiveness of Sterile-Product Compounding. *International Journal of Pharmaceutical Compounding*. 1999; 3: 252-258.



quality. As outlined in Remington's: Pharmaceutical Sciences, there is a much greater degree of uncertainty and inaccuracy involved in end-product testing than in verifying products compounded through accurate process execution.

In addition, "systematic process control relies on prospective data monitoring and collection versus retrospective analysis such as end-product testing. In many cases, the results of end-product testing (sterility or quantitative analysis) are not known prior to product release for patient use,"<sup>5b</sup> as valid test results may require several days to several weeks to obtain. When employing systematic process controls a pharmacy can have a great degree of confidence in the quality of a sterile product prior to obtaining test results. Further, systematic process controls allow for greater diagnostic capabilities in the event an error does occur in a pharmacy operation. Process controls enable the pharmacy to quickly diagnose and correct potential problems in sterile compounding operations.

In addition, endorsement of systematic process controls will reduce costs to Arkansas pharmacies and patients. Testing for sterility, endotoxin level, and potency at an independent laboratory would add approximately \$200-300 to the cost of every batch of sterile products. In-house testing reduces costs only minimally. In order to avoid financial devastation of sterile compounding operations, costs must be passed on to patients in the price of their medications, greatly increasing the cost of quality healthcare. However, according to process control methodology, variables such as sterility, pyrogenicity, and potency are dependent on proper execution of validated processes. Given validated processes, product quality indicators such as sterility, pyrogenicity, and potency should be intrinsic to the product. There would be no need to quantitatively test every batch or product for accuracy. Quantitative end-product testing would instead be performed on a sampling basis, as a double-checking mechanism. This would greatly reduce the amount of capital a pharmacy would need to invest in testing. Likewise, the costs of sampling reflected in a product's price would be greatly reduced.

Overall, validation of processes, personnel, and environment is a much more efficient, economical, and indicative strategy to confirm product quality than end-product testing. The Arkansas Board should consider adopting this alternative regulatory strategy for quality assurance in sterile compounding operations.

In addition to these theoretical concerns, IACP has several substantive concerns with Regulation 07-02-0001 (5). Regulation 07-02-0001 (5), Section (C) should be modified to require potency testing only on a sampling basis. The regulations, as written, place far too much emphasis on potency testing. In many cases, potency testing may not be as critical to a sterile product's safety as testing for sterility and endotoxins. In addition, potency may be effectively verified through process controls, such as checking printed data from balances and adherence to written formulations. Likewise, potency testing for sterile products identified in Regulation 07-02-0001 (5) should be conducted according to a formal sampling plan, as outlined in the pharmacy's policy and procedure manual.

In addition, endorsement of USP methods for sterility and bacterial endotoxin testing in 07-02-0001 (5) (D) precludes the use of in-house testing equipment. Several in-house sterility and endotoxin testing kits are available that may provide pharmacists with appropriate assurance of product quality but may not comply with the extensive requirements of USP <71> and <85>. Compliance with USP <71> and USP <85> would require compounding pharmacies to conduct all testing at independent laboratories. As mentioned previously, independent laboratory testing for sterility, endotoxin level, and potency would add \$200-300 to the cost of every batch. In turn, this would greatly increase costs for both pharmacies and patients. Likewise, the Arkansas Board should review provisions in Section (5) to ensure provision for the use of in-house testing kits and equipment.



**07-02-0002 (l) (8) “Pharmacists may not compound products that are essentially duplicates of FDA-approved products for office stock, unless such drugs are not commercially available. The unavailability of drugs must be documented prior to compounding...”**

The Arkansas Board of Pharmacy has not defined products that are “essentially duplicates of FDA-approved products.” IACP again recommends the congressionally-endorsed definition communicated in our previous discussion of commercially available products. “The term ‘essentially a copy of a commercially available drug product’ does not include a drug product in which there is a change which produces a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.”<sup>1</sup> Without such a definition, this regulation may be the source of arbitrary and overly restrictive enforcement action.

**07-02-0002 (m) (5) “Compounding for office stock for veterinarians is prohibited, except for compounds to be used in life-threatening situations where lack of immediate availability of the product could result in patient harm and no FDA-approved product is commercially available.”**

IACP is extremely concerned with the Arkansas Board of Pharmacy’s extreme prohibition on compounding for office use for veterinarians. Regulation 07-02-0002 (m) (5) is the most restrictive policy on veterinary office use compounding that IACP has seen to date, surpassing many industry and FDA regulations. In Regulation 07-02-0002 (m) (5), the Arkansas Board has implemented a more restrictive standard for animal office use compounding than it has for human patients. The Arkansas Board has not provided any justification for the issuance of such a restrictive policy and IACP suspects that any situation precipitating this regulation may be addressed in another, much less restrictive manner.

In addition, the Board has failed to address many important distinctions in the current provision, such as the distinction between food producing and non-food producing animals. There is no reason for this excessive prohibition against office use compounding for companion or exotic animals. There are many situations that may justify the compounding of office use formulations for such veterinary patients.

It is essential that the Arkansas Board remove Section (m) (5) from Regulation 07-02-0002 to address the issues outlined above. Compounding for office use is an important element of pharmacy practice and the Arkansas Board should continue to allow this practice for veterinary patients.

IACP appreciates the opportunity to share our concerns with the Arkansas Board of Pharmacy and we look forward to working with you to continually advance product quality and, likewise, patient health and safety. If we can be of any assistance as you continue to revise these regulations or if you have any questions, please do not hesitate to contact me or Jennifer Goodrum, IACP’s Regulatory Affairs Coordinator, at (281) 933-8400.

Respectfully submitted,

L.D. King  
Executive Director



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**PROTECTING PROMOTING AND ADVANCING PHARMACY COMPOUNDING**  
*International Academy of Compounding Pharmacists*

IACP002148

**Letter to Texas Board of Pharmacy  
Regarding Veterinary Compounding Policy**

October 3, 2003

Texas State Board of Pharmacy  
c/o Carol Fisher, Director of Enforcement  
333 Guadalupe Street, Suite 3-600  
Austin, TX 78701-3943



International Academy of  
Compounding Pharmacists

**RE: Texas Board of Pharmacy's Enforcement of 21 CFR 530.13**

Dear Ms. Fisher:

The pharmacy organizations listed below have recently become aware of the Texas State Board of Pharmacy's attempted enforcement of 21 CFR 530.13, a federal regulation regarding extralabel drug use in animals. In a recent pharmacy inspection, a Board inspector cited violation of "CFR 530.13" and provided the following explanation: "May not use bulk active pharmaceutical ingredients in compounding veterinary drugs."

While we are unaware of the specifics of this inspection, we would like to address the Texas Board of Pharmacy's interpretation of the federal regulation as a ban on the use of bulk active pharmaceutical ingredients (APIs) to compound for animals.

Initially, we strongly disagree with the Texas Board of Pharmacy's interpretation of 21 CFR 530.13. 21 CFR 530.13 addresses the "compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine." While these regulations do not specifically permit compounding from bulk drug substances, 21 CFR 530.13 also does not specifically prohibit the use of bulk drug substances to compound for animals, a traditional part of the practice of pharmacy. The Texas Board of Pharmacy's citation of 21 CFR 530.13 to justify a ban on compounding from bulk drug substances is inconsistent with the Federal regulation as written.

In addition, the Texas Board of Pharmacy's enforcement of this standard would threaten the health and safety of thousands of animal patients.

Veterinary compounding, including compounding with bulk APIs, remains a vital element of many animals' medication therapies. Veterinary compounding serves a unique population that simply cannot always be treated using commercially available medications. The U.S. Food and Drug Administration (FDA), the author of 21 CFR 530.13, has repeatedly recognized the importance of compounding drugs for animals, inasmuch as the veterinary industry is significantly underserved by existing commercially available drugs. In its veterinary CPG, FDA states, "The current state of veterinary medicine requires products to treat many conditions in a number of different species, some of which are known to have unique physiological characteristics." CPG Sec. 608-400. The reality is that, if pharmacists are limited to using FDA-approved, commercially available drugs to compound products for animals, many animals would die, go untreated, or suffer needlessly.

There are many circumstances that may require pharmacists to compound medications for veterinary patients from bulk drug substances. Situations that require compounding of such products may include:



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IACP002149

- 1) Discontinued Products: commercial products that have been discontinued from the market, not for reasons of safety or effectiveness;
- 2) Product Purity: using finished dosage forms to compound sterile dosage forms may add unnecessary excipients to the compound and increase the risk of pyrogen contamination;
- 3) No Alternative Therapy: There is no commercial alternative to treat the disease state or condition remedied by the compounded product;
- 4) Patient Compliance: a compounded dosage form often improves therapeutic outcomes in animal patients by improving patient compliance.

Our organizations collectively have thousands of compounding pharmacist members, including hundreds of pharmacists who compound in Texas. The industry standard of practice is consistent with the use of bulk APIs to compound for non-food producing animals. Pharmacists must be allowed access to bulk APIs to meet veterinarian and animal patient needs, especially in non-food producing, companion, and exotic animals.

The Texas State Board of Pharmacy has been charged to “promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care.” The Texas State Board of Pharmacy’s broad restriction against the use of bulk APIs to compound for animals would be detrimental to animal health and to the practice of good veterinary medicine. The enforcement of a standard that is detrimental to animal health is clearly inconsistent with the State Board’s mission.

Likewise, we urge the Texas State Board of Pharmacy to reconsider its interpretation of 21 CFR 530.13 as authority to ban the “use of bulk active pharmaceutical ingredients in compounding veterinary drugs.”

Sincerely,

L.D. King, Executive Director  
International Academy of Compounding Pharmacists (IACP)

Jim Martin, Executive Director  
Texas Pharmacy Association (TPA)

Bruce Roberts, Executive Vice President  
National Community Pharmacists Association (NCPA)

cc: Gay Dodson, TSBP Executive Director



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*International Academy of Compounding Pharmacists*

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